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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,724	03/29/2004	Leonard T. Furlow JR.	FUR-100XC1	4815

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,724	FURLOW, LEONARD T.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-10* is/are pending in the application.

4a) Of the above claim(s) *9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/17/07 have been fully considered but they are not persuasive. Regarding the Irie rejection, applicant argues that this patent is directed to inside a blood vessel. The Examiner notes that blood vessels are considered soft tissue as stated by Wikipedia.

Soft tissue

From Wikipedia, the free encyclopedia
Jump to: navigation, search

In medicine, the term **soft tissue** refers to tissues that connect, support, or surround other structures and organs of the body. Soft tissue includes muscles, fibrous tissues, fat, blood vessels, and synovial tissues.[1]

Additionally, the resulting embolism would at least result in a fiburous tissue growth into the cylinder.

Regarding the rejection in view of Ersek et al, applicant states that the pellets have a defined shape and a conduit running through the pellet. The Examiner notes that applicant's specification teaches "*the pellets may be any shape, so long as they have a hollow space running therethrough*". Applicant specific states shape does not matter! Regarding the conduit therethrough, see figure 2, elements 11; note the teaching of an open diameter dimension of up to about 500 microns (6:39 et seq.) which is within applicant's taught range for ingrowth of capillaries and fibrous tissue.

Specification

The amendment filed 10/17/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New drawings 1 and 2 and the brief description of said figures is new matter. Applicant failed to indicate wherein the original disclosure support could be found. New matter includes diameter and/or length of the cylinders, size of opening, sterile fluid.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pellets and injection device as claimed must be shown or the feature(s) canceled from the claim(s). **No new matter should be entered.**

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 6, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Irie (5,895,411).

Irie teaches:

1. A method for soft tissue augmentation (see 1:12 et seq.) wherein said method comprises the placement of hollow-cylinder pellets (24, note the teaching of an inner A and outer B diameter) in a location where augmentation is desired.

Claim 7, the catheter 20 and pusher 26 are interpreted as a syringe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al (5,336,263).

Ersek et al teaches a method for soft tissue augmentation wherein said method comprises the placement of hollow pellets (see figure 2) in a location where augmentation is desired. However, Ersek et al fails to teach the hollow pellets are hollow-cylinder pellets or doughnut-shaped.

Applicant's specification teaches:

"[0013] In a preferred embodiment, the subject invention involves the injection of hollow-cylinder pellets such as, for example, doughnut-shaped pellets, to a site where soft tissue augmentation is desired. The pellets may be any shape, so long as they have a hollow space running therethrough. In additional embodiments, the pellets could also be, for example, spherical (or any other shape) with a hollow tunnel passing therethrough."

Applicant has not disclosed that claimed shape provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the shape taught by Ersek et al or the claimed shape because both prevent loss of the particles from the injection site (see abstract).

All other claim limitations are self-evident.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's specification in view of Ersek et al (5,336,263).

Applicant's specification teaches that for velopharyngeal insufficiency the follow is known:

"The simplest method has been to place a fluid material such as silicone or a paste of Teflon ***particles*** *by injection. However, because of the potential for migration of the materials away from the site of injection (with loss of the mound) to lymph nodes, tissue planes or even lungs or brain, these methods have not gained approval for clinical use. (2:7 et seq.)".*

Therefore, it would have been obvious to having ordinary skill in the art to have utilized/tried the pellets of Ersek et al in the known method to prevent possible migration

because the shape of Ersek et al prevents loss of the particles from the injection site (see abstract and 7:17 et seq.).

Regarding the claimed shape, as established in the grounds of rejection above, applicant has not disclosed that claimed shape provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the shape taught by Ersek et al or the claimed shape because both prevent loss of the particles from the injection site (see abstract).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

BRUCE SNOW
PRIMARY EXAMINER